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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,006	12/19/2000	Johann Karl	RDID00115US	5872

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EXAMINER
PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
1641	8

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,006	KARL ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *44-69* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that both groups are drawn to detection of heterogeneous populations. This is not found persuasive because the detection of a heterogeneous population is not required of Group I. In addition, applicant's assertion that claim 45 recites detection in a heterogeneous population is erroneous, as a mixture of molecules in part of a Markush group and is therefore not required of the claim.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables

having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.
(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Applicant should insert section headings for the relevant sections of the disclosure.

3. The use of the trademark Enzymun has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 44-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 44 recites the limitations "the detection" in line 1, "the case" in lines 7 and 8, and "the presence" in line 15. There is insufficient antecedent basis for these limitations in the claim. In addition, the recitations of the term "capable" in lines 5, 12, and 13 render the claim vague and indefinite because it is unclear if binding is actually required of the claim or not.

7. Claim 49 recites the limitations "the detection" in line 1 and "the case" in lines 5-6 and 7. There is insufficient antecedent basis for these limitations in the claim. In addition, the recitation of the term "capable" renders the claim vague and indefinite because it is unclear if binding is actually required of the claim or not.

8. Claim 51 recites the limitation "the detection" in line 1. There is insufficient antecedent basis for this limitation in the claim. In addition, the recitations of the term "capable" render the claim vague and indefinite because it is unclear if binding is actually required of the claim or not.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 44-45, 47, 49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Fish et al. (US Pat. 5,126,276). The reference discloses methods and kits for the determinations of analytes, such as antigens and antibodies, in multiple samples. The method comprises providing a receptor for the analyte at more than one location on a solid substrate, exposing each of the receptors to different samples, and developing each of the receptor locations to indicate analyte presence. The substrate is preferably in the form of a card comprising a plurality of tabs, wherein a control may be provided on one of the tabs (Col. 3). The solid phase support of the

reference may be made of polystyrene, which is inherently non-porous (Col. 6, lines 47-55). The receptors may be bound to the support either directly or indirectly (Col. 6, line 64-Col. 7, line 24). Exposure of the analyte-containing support may be performed through exposure to a probe-containing solution. The probe is generally a labeled receptor (Col. 9, lines 1-22). The reference discloses that a number of labels may be used with the method of the reference.

11. Claims 44-46 and 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Ekins (US Pat. 5,432,099). The reference discloses methods and kits for the determination of various analytes. The method comprises loading a plurality of different binding agents onto a support at a plurality of spaced apart locations, contacting the support with a sample such that any analyte in the sample binds to its specific binding agent on the support, and using competitive or non-competitive techniques with a site-recognition agent labeled with a marker to determine analyte presence (Col. 4, lines 19-50). The reference discloses that the support is preferably non-porous (Col. 5, lines 42-45). The binding agents of the reference are preferably antibodies, and any known label may be used (Col. 6, lines 44-60). The binding agents may be applied to the support as drops on a spot, which is preferably less than 1 square millimeter (Col. 7, lines 4-31).

12. Claims 44-45, 47, 49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Connor et al. (US Pat. 5,627,026). The reference discloses detection of an antigen and antibody in a sample. The method comprises providing an antigen and antibody on two discrete locations on a solid support, contacting the support with the test locations with a sample under conditions that allow immune complexes to form, and detecting the presence of complex formation at both locations using labeled molecules that bind to the complexes (Col. 9, lines 40-

65). The solid support of the reference is preferably a microtiter well, a glass or plastic bead, or a polystyrene latex bead, all of which are inherently non-porous (Col. 2, lines 65-67). The method also comprises a control spot.

13. Claims 44-45, 47, 49, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Chan et al. (EP 0 461 462 A1). The reference discloses a solid phase immunoassay that can simultaneously detect a number of different antigens. A test sample is contacted with a solid support on which one or more antigens are immobilized at discrete test sites. The discrete test sites may be immunodot blots. The antigen-antibody complexes may be detected by contacting the complexes with a conjugated signal generating system (Page 4, lines 7-17). A procedural control may be included on the support. In addition, the support of the reference may be latex and rubber, which are non-porous (Page 5, lines 16-40).

14. Claims 44-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Ekins et al. (WO 93/08472). The reference discloses a binding assay and kit. The assay may use a microspot technique that allows for determination of different analytes in a single operation. Different binding agents are immobilized on different microspots on the same solid support and are developed with labeled microspheres (Page 9, lines 12-20). The microspheres may be made of polymer latex and be labeled with various markers (Page 6, lines 15-33). The microspots may have a diameter of 0.01-1 mm (Page 8, lines 28-35). The capture binding agents may be antibodies, and the analyte of interest may be an antigen. The solid support of the reference may be polystyrene microtiter wells, which are inherently non-porous (Page 25, line 7). The method and kit of the reference may also include standards deposited on the substrate (Page 26, example 6).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 46, 48, 50, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fish et al. (US Pat. 5,126,276). The reference teaches methods and kits for analyte determination, as previously discussed under 35 USC 102. However, the reference does not teach the diameter of the test area or the use of latex particles as the label.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use test areas with diameters less than 1 mm and latex particles as the label with the method and kit of Fish et al. One would have been motivated to do so because the use of test areas with a small diameter allows for a greater number of receptors to placed on the substrate, or alternatively, allows for the use of smaller substrates. In addition, since the reference teaches that any suitable label may be used, one could have used latex particles with a reasonable expectation of success. Further, the selection of test areas with a specific diameter and a specific label both represent simple optimizations of the assay protocol that one of skill in the art could have easily chosen based on preference.

19. Claims 47-48 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekins (US Pat. 5,432,099). The reference teaches methods and kits for analyte determination, as previously discussed under 35 USC 102. However, the reference does not teach a control area or the use of latex particles as the label.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a control area and latex particles as the label with the method and kit of Ekins. One would have been motivated to do so because the use of a control area allows determination of background or baseline, which permits calibration of the assay system and a more sensitive measurement of analyte presence. In addition, since the reference teaches that any suitable label may be used, one could have used latex particles with a reasonable expectation of success. Further, the selection of a specific label simple represents an optimization of the assay protocol that one of skill in the art could have easily chosen based on preference.

20. Claims 46, 48, 50, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. (US Pat. 5,627,026). The reference teaches methods and kits for analyte determination, as previously discussed under 35 USC 102. However, the reference does not teach the diameter of the test area or the use of latex particles as the label.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use test areas with diameters less than 1 mm and latex particles as the label with the method and kit of O'Connor et al. One would have been motivated to do so because the use of test areas with a small diameter allows for a greater number of receptors to placed on the substrate, or alternatively, allows for the use of smaller substrates. In addition, since the reference teaches that any suitable label may be used, one could have used latex particles with a reasonable expectation of success. Further, the selection of test areas with a specific diameter and a specific label both represent simple optimizations of the assay protocol that one of skill in the art could have easily chosen based on preference.

21. Claims 46, 48, 50, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. (EP 0 461 462 A1). The reference teaches methods and kits for analyte determination, as previously discussed under 35 USC 102. However, the reference does not teach the diameter of the test area or the use of latex particles as the label.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use test areas with diameters less than 1 mm and latex particles as the label with the method and kit of Chan et al. One would have been motivated to do so because the use of test areas with a small diameter allows for a greater number of receptors to placed on the substrate, or alternatively, allows for the use of smaller substrates. In addition, since the

reference teaches that any suitable label may be used, one could have used latex particles with a reasonable expectation of success. Further, the selection of test areas with a specific diameter and a specific label both represent simple optimizations of the assay protocol that one of skill in the art could have easily chosen based on preference. In fact, the reference specifically states that the choice of label may be determined by the "routineer." (Page 6, lines 20-21).

Conclusion

Claims 44-52 are rejected.

References: Obremski et al., Simpson et al., and McMahon et al. are cited as art of interest for teaching various multianalyte immunoassay designs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641
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December 2, 2002

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SUPERVISORY PATENT EXAMINER
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12/02/02